



January 22, 2016

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## SENATE BILL No. 41

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DIGEST OF SB 41 (Updated January 20, 2016 12:45 pm - DI 104)

**Citations Affected:** IC 5-10; IC 27-8; IC 27-13.

**Synopsis:** Pharmacy benefits. Specifies requirements for the establishment and use of a prescription drug step therapy protocol by a state employee health plan, an accident and sickness insurer, or a health maintenance organization.

**Effective:** July 1, 2016.

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### Crider, Brown L, Stoops

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January 5, 2016, read first time and referred to Committee on Rules & Legislative Procedure.

January 11, 2016, amended; reassigned to Committee on Health & Provider Services.

January 21, 2016, amended, reported favorably — Do Pass.

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SB 41—LS 6169/DI 13





January 22, 2016

Second Regular Session 119th General Assembly (2016)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type~~.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~this style type~~ reconciles conflicts between statutes enacted by the 2015 Regular Session of the General Assembly.

## SENATE BILL No. 41

A BILL FOR AN ACT to amend the Indiana Code concerning insurance.

*Be it enacted by the General Assembly of the State of Indiana:*

- 1 SECTION 1. IC 5-10-8-17 IS ADDED TO THE INDIANA CODE
- 2 AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY
- 3 1, 2016]: **Sec. 17. (a) As used in this section, "clinical practice**
- 4 **guidelines" means systematically developed recommendations**
- 5 **intended for use by health care providers in determining the**
- 6 **appropriate care for a clinical condition.**
- 7 **(b) As used in this section, "covered individual" means an**
- 8 **individual entitled to coverage under a state employee health plan.**
- 9 **(c) As used in this section, "department" refers to the**
- 10 **department of insurance created by IC 27-1-1-1.**
- 11 **(d) As used in this section, "medical necessity" or "medically**
- 12 **necessary" means appropriateness, or appropriate, under the**
- 13 **standard of care that applies to a covered individual's condition:**
- 14 **(1) to improve, preserve, or slow the deterioration of the**
- 15 **covered individual's health, life, or function; or**
- 16 **(2) for the early screening, prevention, evaluation, diagnosis,**
- 17 **or treatment of the covered individual's condition or injury.**

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(e) As used in this section, "preceding prescription drug" means a prescription drug that, according to a step therapy protocol, must be:

- (1) first used to treat a covered individual's condition; and
- (2) as a result of the treatment under subdivision (1), determined to be inappropriate to treat the covered individual's condition;

as a condition of coverage under a state employee health plan for succeeding treatment with another prescription drug.

(f) As used in this section, "protocol exception" means a determination by a state employee health plan that, based on a review of a request for the determination and any supporting documentation:

- (1) a step therapy protocol is not medically appropriate for treatment of a particular covered individual's condition; and
- (2) the state employee health plan will:
  - (A) not require the covered individual's use of a preceding prescription drug under the step therapy protocol; and
  - (B) provide immediate coverage for another prescription drug that is prescribed for the covered individual.

(g) As used in this section, "state employee health plan" refers to the following that provide coverage for prescription drugs:

- (1) A self-insurance program established under section 7(b) of this chapter.
- (2) A contract with a prepaid health care delivery plan that is entered into or renewed under section 7(c) of this chapter.

The term includes a person that administers prescription drug benefits on behalf of a state employee health plan.

(h) As used in this section, "step therapy protocol" means a protocol that specifies, as a condition of coverage under a state employee health plan, the order in which certain prescription drugs must be used to treat a covered individual's condition.

(i) A state employee health plan shall base a step therapy protocol on clinical practice guidelines to which the following apply:

- (1) The clinical practice guidelines recommend that the prescription drugs be taken in the specific order required by the step therapy protocol.
- (2) The clinical practice guidelines are developed and endorsed by a multidisciplinary panel of experts that manages conflicts of interest among the members of the clinical practice guideline writing and review groups by:



- 1 (A) requiring each member to:
- 2 (i) disclose any potential conflicts of interest involving
- 3 other persons, including insurers, other third party
- 4 payers, and pharmaceutical manufacturers; and
- 5 (ii) recuse the member from voting if the member has a
- 6 conflict of interest;
- 7 (B) using a methodologist to work with clinical practice
- 8 guideline writing groups to provide objectivity in:
- 9 (i) data analysis;
- 10 (ii) evidence ranking through preparation of evidence
- 11 tables; and
- 12 (iii) consensus facilitation; and
- 13 (C) offering opportunities for public review of and
- 14 comment on proposed clinical practice guidelines.
- 15 (3) The clinical practice guidelines are based on high quality
- 16 studies, research, and medical practice.
- 17 (4) The clinical practice guidelines are created by an explicit
- 18 and publicly available process that:
- 19 (A) minimizes bias and conflict of interest;
- 20 (B) explains the relationship between treatment options
- 21 and outcomes;
- 22 (C) rates the quality of the evidence supporting
- 23 recommendations; and
- 24 (D) considers relevant patient subgroups and preferences.
- 25 (5) The clinical practice guidelines are continually updated
- 26 through a review of new evidence, research, and newly
- 27 developed treatments.
- 28 However, in the absence of clinical practice guidelines that meet
- 29 the requirements of this subsection, a state employee health plan
- 30 may base a step therapy protocol on applicable peer reviewed
- 31 publications.
- 32 (j) A state employee health plan shall:
- 33 (1) annually certify to the department that the state employee
- 34 health plan has complied with this chapter; and
- 35 (2) before using a step therapy protocol:
- 36 (A) file the step therapy protocol and supporting
- 37 documentation with the department; and
- 38 (B) obtain approval of the step therapy protocol by the
- 39 department.
- 40 (k) A state employee health plan shall publish on the state
- 41 employee health plan's Internet web site, and provide to a covered
- 42 individual in writing, a procedure for the covered individual's use



1 in requesting a protocol exception. The procedure must include the  
 2 following provisions:

3 (1) A description of the manner in which a covered individual  
 4 may request a protocol exception.

5 (2) That the state employee health plan shall make a  
 6 determination concerning a protocol exception request, or an  
 7 appeal of a denial of a protocol exception request, not more  
 8 than:

9 (A) in the case of an emergency, twenty-four (24) hours  
 10 after receiving the request or appeal; or

11 (B) in the case of a nonemergency, seventy-two (72) hours  
 12 after receiving the request or appeal.

13 (3) That if the state employee health plan does not notify the  
 14 covered individual of the state employee health plan's  
 15 determination within the required time specified in  
 16 subdivision (2), the request or appeal is considered to have  
 17 been decided in favor of the covered individual.

18 (4) That a protocol exception will be granted if any of the  
 19 following apply, as determined by the covered individual's  
 20 treating health care provider:

21 (A) Following the step therapy protocol is contraindicated  
 22 or will likely cause an adverse reaction or physical or  
 23 mental harm to the covered individual.

24 (B) A preceding prescription drug is expected to be  
 25 ineffective based on the known clinical characteristics of  
 26 the covered individual and the known characteristics of the  
 27 prescription drug regimen.

28 (C) The covered individual has previously received:

29 (i) a preceding prescription drug; or

30 (ii) another prescription drug that is in the same  
 31 pharmacologic class or has the same mechanism of  
 32 action as a preceding prescription drug;

33 and the prescription drug was discontinued due to lack of  
 34 efficacy or effectiveness, diminished effect, or an adverse  
 35 event.

36 (D) Based on medical necessity, a preceding prescription  
 37 drug is not in the best interest of the covered individual.

38 (E) The covered individual's condition is currently stable  
 39 on a prescription drug prescribed by the covered  
 40 individual's health care provider before implementation or  
 41 applicability of the step therapy protocol.

42 (5) That when a protocol exception is granted, the state



employee health plan shall notify the covered individual and the covered individual's health care provider of the authorization for coverage of the prescription drug that is the subject of the protocol exception.

(l) This section does not do the following:

(1) Prevent a state employee health plan from requiring a covered individual to use a generic prescription drug that has been classified by the federal Food and Drug Administration and published in its Approved Drug Products with Therapeutic Equivalence Evaluations list as having a therapeutic equivalence evaluation of "AB" with the prescribed brand name prescription drug before providing coverage for the prescribed brand name prescription drug.

(2) Prevent a health care provider from prescribing a prescription drug that is determined to be medically necessary.

(m) The department may adopt rules under IC 4-22-2 to implement this section.

SECTION 2. IC 27-8-5-30 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 30. (a) As used in this section, "clinical practice guidelines" means systematically developed recommendations intended for use by health care providers in determining the appropriate care for a clinical condition.

(b) As used in this section, "department" refers to the department of insurance created by IC 27-1-1-1.

(c) As used in this section, "insured" means an individual who is entitled to coverage under a policy of accident and sickness insurance.

(d) As used in this section, "insurer" refers to an insurer that issues a policy of accident and sickness insurance. The term includes a person that administers prescription drug benefits on behalf of an insurer.

(e) As used in this section, "medical necessity" or "medically necessary" means appropriateness, or appropriate, under the standard of care that applies to an insured's condition:

(1) to improve, preserve, or slow the deterioration of the insured's health, life, or function; or

(2) for the early screening, prevention, evaluation, diagnosis, or treatment of the insured's condition or injury.

(f) As used in this section, "policy of accident and sickness insurance" means a policy of accident and sickness insurance that



provides coverage for prescription drugs.

(g) As used in this section, "preceding prescription drug" means a prescription drug that, according to a step therapy protocol, must be:

- (1) first used to treat an insured's condition; and
- (2) as a result of the treatment under subdivision (1), determined to be inappropriate to treat the insured's condition;

as a condition of coverage under a policy of accident and sickness insurance for succeeding treatment with another prescription drug.

(h) As used in this section, "protocol exception" means a determination by an insurer that, based on a review of a request for the determination and any supporting documentation:

- (1) a step therapy protocol is not medically appropriate for treatment of a particular insured's condition; and
- (2) the insurer will:
  - (A) not require the insured's use of a preceding prescription drug under the step therapy protocol; and
  - (B) provide immediate coverage for another prescription drug that is prescribed for the insured.

(i) As used in this section, "step therapy protocol" means a protocol that specifies, as a condition of coverage under a policy of accident and sickness insurance, the order in which certain prescription drugs must be used to treat an insured's condition.

(j) An insurer shall base a step therapy protocol on clinical practice guidelines to which the following apply:

- (1) The clinical practice guidelines recommend that the prescription drugs be taken in the specific order required by the step therapy protocol.
- (2) The clinical practice guidelines are developed and endorsed by a multidisciplinary panel of experts that manages conflicts of interest among the members of the clinical practice guideline writing and review groups by:
  - (A) requiring each member to:
    - (i) disclose any potential conflicts of interest involving other persons, including insurers, other third party payers, and pharmaceutical manufacturers; and
    - (ii) recuse the member from voting if the member has a conflict of interest;
  - (B) using a methodologist to work with clinical practice guideline writing groups to provide objectivity in:



- 1 (i) data analysis;
- 2 (ii) evidence ranking through preparation of evidence
- 3 tables; and
- 4 (iii) consensus facilitation; and
- 5 (C) offering opportunities for public review of and
- 6 comment on proposed clinical practice guidelines.
- 7 (3) The clinical practice guidelines are based on high quality
- 8 studies, research, and medical practice.
- 9 (4) The clinical practice guidelines are created by an explicit
- 10 and publicly available process that:
- 11 (A) minimizes bias and conflict of interest;
- 12 (B) explains the relationship between treatment options
- 13 and outcomes;
- 14 (C) rates the quality of the evidence supporting
- 15 recommendations; and
- 16 (D) considers relevant patient subgroups and preferences.
- 17 (5) The clinical practice guidelines are continually updated
- 18 through a review of new evidence, research, and newly
- 19 developed treatments.
- 20 However, in the absence of clinical practice guidelines that meet
- 21 the requirements of this subsection, an insurer may base a step
- 22 therapy protocol on applicable peer reviewed publications.
- 23 (k) An insurer shall:
- 24 (1) annually certify to the department that the insurer has
- 25 complied with this chapter; and
- 26 (2) before using a step therapy protocol:
- 27 (A) file the step therapy protocol and supporting
- 28 documentation with the department; and
- 29 (B) obtain approval of the step therapy protocol by the
- 30 department.
- 31 (l) An insurer shall publish on the insurer's Internet web site,
- 32 and provide to an insured in writing, a procedure for the insured's
- 33 use in requesting a protocol exception. The procedure must include
- 34 the following provisions:
- 35 (1) A description of the manner in which an insured may
- 36 request a protocol exception.
- 37 (2) That the insurer shall make a determination concerning a
- 38 protocol exception request, or an appeal of a denial of a
- 39 protocol exception request, not more than:
- 40 (A) in the case of an emergency, twenty-four (24) hours
- 41 after receiving the request or appeal; or
- 42 (B) in the case of a nonemergency, seventy-two (72) hours



- 1 after receiving the request or appeal.
- 2 (3) That if the insurer does not notify the insured of the
- 3 insurer's determination within the required time specified in
- 4 subdivision (2), the request or appeal is considered to have
- 5 been decided in favor of the insured.
- 6 (4) That a protocol exception will be granted if any of the
- 7 following apply, as determined by the insured's treating
- 8 health care provider:
- 9 (A) Following the step therapy protocol is contraindicated
- 10 or will likely cause an adverse reaction or physical or
- 11 mental harm to the insured.
- 12 (B) A preceding prescription drug is expected to be
- 13 ineffective based on the known clinical characteristics of
- 14 the insured and the known characteristics of the
- 15 prescription drug regimen.
- 16 (C) The insured has previously received:
- 17 (i) a preceding prescription drug; or
- 18 (ii) another prescription drug that is in the same
- 19 pharmacologic class or has the same mechanism of
- 20 action as a preceding prescription drug;
- 21 and the prescription drug was discontinued due to lack of
- 22 efficacy or effectiveness, diminished effect, or an adverse
- 23 event.
- 24 (D) Based on medical necessity, a preceding prescription
- 25 drug is not in the best interest of the insured.
- 26 (E) The insured's condition is currently stable on a
- 27 prescription drug prescribed by the insured's health care
- 28 provider before implementation or applicability of the step
- 29 therapy protocol.
- 30 (5) That when a protocol exception is granted, the insurer
- 31 shall notify the insured and the insured's health care provider
- 32 of the authorization for coverage of the prescription drug that
- 33 is the subject of the protocol exception.
- 34 (m) This section does not do the following:
- 35 (1) Prevent an insurer from requiring an insured to use a
- 36 generic prescription drug that has been classified by the
- 37 federal Food and Drug Administration and published in its
- 38 Approved Drug Products with Therapeutic Equivalence
- 39 Evaluations list as having a therapeutic equivalence
- 40 evaluation of "AB" with the prescribed brand name
- 41 prescription drug before providing coverage for the
- 42 prescribed brand name prescription drug.



(2) Prevent a health care provider from prescribing a prescription drug that is determined to be medically necessary.

(o) The department may adopt rules under IC 4-22-2 to implement this section.

SECTION 3. IC 27-13-7-23 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 23. (a) As used in this section, "clinical practice guidelines" means systematically developed recommendations intended for use by health care providers in determining the appropriate care for a clinical condition.

(b) As used in this section, "group contract" refers to a group contract that provides coverage for prescription drugs.

(c) As used in this section, "health maintenance organization" refers to a health maintenance organization that provides coverage for prescription drugs. The term includes the following:

(1) A limited service health maintenance organization.

(2) A person that administers prescription drug benefits on behalf of a health maintenance organization or a limited service health maintenance organization.

(d) As used in this section, "individual contract" refers to an individual contract that provides coverage for prescription drugs.

(e) As used in this section, "medical necessity" or "medically necessary" means appropriateness, or appropriate, under the standard of care that applies to an enrollee's condition:

(1) to improve, preserve, or slow the deterioration of the enrollee's health, life, or function; or

(2) for the early screening, prevention, evaluation, diagnosis, or treatment of the enrollee's condition or injury.

(f) As used in this section, "preceding prescription drug" means a prescription drug that, according to a step therapy protocol, must be:

(1) first used to treat an enrollee's condition; and

(2) as a result of the treatment under subdivision (1), determined to be inappropriate to treat the enrollee's condition;

as a condition of coverage under an individual contract or a group contract for succeeding treatment with another prescription drug.

(g) As used in this section, "protocol exception" means a determination by a health maintenance organization that, based on a review of a request for the determination and any supporting documentation:



1 (1) a step therapy protocol is not medically appropriate for  
 2 treatment of a particular enrollee's condition; and

3 (2) the health maintenance organization will:

4 (A) not require the enrollee's use of a preceding  
 5 prescription drug under the step therapy protocol; and

6 (B) provide immediate coverage for another prescription  
 7 drug that is prescribed for the enrollee.

8 (h) As used in this section, "step therapy protocol" means a  
 9 protocol that specifies, as a condition of coverage under an  
 10 individual contract or a group contract, the order in which certain  
 11 prescription drugs must be used to treat an enrollee's condition.

12 (i) A health maintenance organization shall base a step therapy  
 13 protocol on clinical practice guidelines to which the following  
 14 apply:

15 (1) The clinical practice guidelines recommend that the  
 16 prescription drugs be taken in the specific order required by  
 17 the step therapy protocol.

18 (2) The clinical practice guidelines are developed and  
 19 endorsed by a multidisciplinary panel of experts that manages  
 20 conflicts of interest among the members of the clinical  
 21 practice guideline writing and review groups by:

22 (A) requiring each member to:

23 (i) disclose any potential conflicts of interest involving  
 24 other persons, including insurers, other third party  
 25 payers, and pharmaceutical manufacturers; and

26 (ii) recuse the member from voting if the member has a  
 27 conflict of interest;

28 (B) using a methodologist to work with clinical practice  
 29 guideline writing groups to provide objectivity in:

30 (i) data analysis;

31 (ii) evidence ranking through preparation of evidence  
 32 tables; and

33 (iii) consensus facilitation; and

34 (C) offering opportunities for public review of and  
 35 comment on proposed clinical practice guidelines.

36 (3) The clinical practice guidelines are based on high quality  
 37 studies, research, and medical practice.

38 (4) The clinical practice guidelines are created by an explicit  
 39 and publicly available process that:

40 (A) minimizes bias and conflict of interest;

41 (B) explains the relationship between treatment options  
 42 and outcomes;



(C) rates the quality of the evidence supporting recommendations; and

(D) considers relevant patient subgroups and preferences.

(5) The clinical practice guidelines are continually updated through a review of new evidence, research, and newly developed treatments.

However, in the absence of clinical practice guidelines that meet the requirements of this subsection, a health maintenance organization may base a step therapy protocol on applicable peer reviewed publications.

(j) A health maintenance organization shall:

(1) annually certify to the department that the health maintenance organization has complied with this chapter; and

(2) before using a step therapy protocol:

(A) file the step therapy protocol and supporting documentation with the department; and

(B) obtain approval of the step therapy protocol by the department.

(k) A health maintenance organization shall publish on the health maintenance organization's Internet web site, and provide to an enrollee in writing, a procedure for the enrollee's use in requesting a protocol exception. The procedure must include the following provisions:

(1) A description of the manner in which an enrollee may request a protocol exception.

(2) That the health maintenance organization shall make a determination concerning a protocol exception request, or an appeal of a denial of a protocol exception request, not more than:

(A) in the case of an emergency, twenty-four (24) hours after receiving the request or appeal; or

(B) in the case of a nonemergency, seventy-two (72) hours after receiving the request or appeal.

(3) That if the health maintenance organization does not notify the enrollee of the health maintenance organization's determination within the required time specified in subdivision (2), the request or appeal is considered to have been decided in favor of the enrollee.

(4) That a protocol exception will be granted if any of the following apply, as determined by the enrollee's treating health care provider:

(A) Following the step therapy protocol is contraindicated



1 or will likely cause an adverse reaction or physical or  
2 mental harm to the enrollee.

3 (B) A preceding prescription drug is expected to be  
4 ineffective based on the known clinical characteristics of  
5 the enrollee and the known characteristics of the  
6 prescription drug regimen.

7 (C) The enrollee has previously received:

8 (i) a preceding prescription drug; or

9 (ii) another prescription drug that is in the same  
10 pharmacologic class or has the same mechanism of  
11 action as a preceding prescription drug;

12 and the prescription drug was discontinued due to lack of  
13 efficacy or effectiveness, diminished effect, or an adverse  
14 event.

15 (D) Based on medical necessity, a preceding prescription  
16 drug is not in the best interest of the enrollee.

17 (E) The enrollee's condition is currently stable on a  
18 prescription drug prescribed by the enrollee's health care  
19 provider before implementation or applicability of the step  
20 therapy protocol.

21 (5) That when a protocol exception is granted, the health  
22 maintenance organization shall notify the enrollee and the  
23 enrollee's health care provider of the authorization for  
24 coverage of the prescription drug that is the subject of the  
25 protocol exception.

26 (m) This section does not do the following:

27 (1) Prevent a health maintenance organization from requiring  
28 an enrollee to use a generic prescription drug that has been  
29 classified by the federal Food and Drug Administration and  
30 published in its Approved Drug Products with Therapeutic  
31 Equivalence Evaluations list as having a therapeutic  
32 equivalence evaluation of "AB" with the prescribed brand  
33 name prescription drug before providing coverage for the  
34 prescribed brand name prescription drug.

35 (2) Prevent a health care provider from prescribing a  
36 prescription drug that is determined to be medically  
37 necessary.

38 (n) The department may adopt rules under IC 4-22-2 to  
39 implement this section.



COMMITTEE REPORT

Madam President: The Senate Committee on Rules and Legislative Procedure, to which was referred Senate Bill No. 41, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Delete the title and insert the following:

A BILL FOR AN ACT to amend the Indiana Code concerning insurance.

Delete everything after the enacting clause and insert the following:

(SEE TEXT OF BILL)

and when so amended that said bill be reassigned to the Senate Committee on Health & Provider Services.

(Reference is to SB 41 as introduced.)

LONG, Chairperson

COMMITTEE REPORT

Madam President: The Senate Committee on Health and Provider Services, to which was referred Senate Bill No. 41, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Page 4, line 19, delete ":" and insert ", **as determined by the covered individual's treating health care provider:**".

Page 8, line 6, delete ":" and insert ", **as determined by the insured's treating health care provider:**".

Page 11, line 38, delete ":" and insert ", **as determined by the enrollee's treating health care provider:**".

and when so amended that said bill do pass.

(Reference is to SB 41 as printed January 12, 2016.)

MILLER PATRICIA, Chairperson

Committee Vote: Yeas 10, Nays 1.

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